

**REMARKS**

Applicants respectfully request reconsideration of the present application in view of the reasons that follow.

**I. Status of Claims and Amendments**

Claim 18 is canceled without prejudice or disclaimer.

Upon entry of the amendments, claims 2, 6-12, 15-17, and 19-27 will be pending and subject to examination on the merits.

**II. Claim Rejections/Objections**

The Examiner objects to claim 18 as an improper dependent claim. Applicant has canceled claim 18 thereby rendering this ground of objection moot.

**III. Claim Rejections under 35 U.S.C. § 103(a)**

**A. U.S. Patent No. 6,090,292 to Zimmerman *et al.* in view of U.S. Patent No. 6,036,861 to Flickinger**

Claims 2, 6-8, 11-12, 15-21 and 24-27 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 6,090,292 to Zimmerman *et al.* in view of U.S. Patent No. 6,036,861 to Flickinger. The Office Action contends that it would be obvious “to modify the extracorporeal adsorption method using fluidized bed adsorption as taught by Zimmerman *et al.*, where the modification incorporates the particles having a density of at least 1.3 g/ml, a diameter in a range of 5-1000  $\mu$ m and where the sedimented volume is at most 80% as taught Flickinger *et al.*, in order to provide a significantly high and surprisingly substantially consistent dynamic protein binding capacity when expanded at high fluid velocity that also rapidly adsorb proteins.” Office Action at pgs. 7-8. Applicants respectfully traverse this ground of rejection.

The rejection is premised on the conclusion that Zimmerman teaches the use of “fluidized bed adsorption,” as claimed. Yet this interpretation of Zimmerman is incorrect.

Zimmerman relates to the use of a *packed bed column* containing rather large particles. These large particles are sedimented in the column, and fluid flows downward through the particles. (Zimmerman at Figs. 1 and 2). The specification specifically describes what is meant by a “fluidized bed.” *See spec. at pg. 18, ll. 24-32.* And this description distinguishes packed bed columns, such as those described by Zimmerman, from fluidized beds. Because of Zimmerman’s packed bed column design, Zimmerman does not describe “a flow rate [such] that a fluidised bed of the particles is formed,” as recited by claim 2.

Moreover, one of skill in the art would not expect Zimmerman’s column to allow “blood [to] pass[] through and exit[] the column.” Zimmerman’s large particles may allow some blood cells to pass the column. Nonetheless, one of skill in the art would expect Zimmerman’s column to gradually clog and show serious decrease in functionality in the time required for adequate removal of the harmful substances.

Flickinger generally relates to the protein adsorption particles and, along those lines, discloses fluidized bed adsorption columns. But Flickinger does not disclose extracorporeal adsorption “for removing harmful substances responsible of inducing sepsis caused by Gram-negative or Gram-positive bacteria,” as claimed, or even suggest that its particles could be used in that application. And one of skill in the art would not necessarily expect that the types of adsorption columns would be interchangeable due to the very different properties of the columns. Thus, Flickinger and Zimmerman do not teach or suggest the claimed method.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

**B. Jaber et al. (American Journal of Kidney diseases. Vol. 30, No. 5, Suppl. 4 (November), 1997: pp. S44-S56 in view of U.S. Patent No. 6,036,861 to Flickinger**

Claims 2, 6-7, 9-10, 16-18, 20-23 and 26-27 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Jaber et al. (American Journal of Kidney diseases. Vol. 30, No. 5, Suppl. 4 (November), 1997: pp. S44-S56 in view of U.S. Patent No. 6,036,861 to Flickinger. Applicants respectfully traverse this ground of rejection.

Like Zimmerman, Jaber fails to disclose the use of fluidized bed adsorption columns, as recited by the claims. Jaber discloses hemoperfusion methods using fiber cartridges where the flow rate was 80-100 ml/min (page S50, 2<sup>nd</sup> col.) as well as flow rates in other packed columns with flow rates between 70-200 ml/min (page S53 generally). Nowhere in Jaber is there a discussion of fluidized bed adsorption columns as presently recited; nor is there an indication that anything other than a standard packed column is used. Indeed, the high flow rates suggest Jaber's methodology is far removed from the gentle, fluidized adsorption of the presently claimed invention.

Flickinger generally relates to the protein adsorption particles and, along those lines, does disclose fluidized bed adsorption columns, as noted above. But Flickinger does not disclose extracorporeal adsorption "for removing harmful substances responsible of inducing sepsis caused by Gram-negative or Gram-positive bacteria," as claimed. Simply substitution of the columns would not be obvious due to the very different characteristics of the columns. Thus, Flickinger and Zimmerman do not teach or suggest the claimed method.

The Office Action states that one of skill in the art would have a reasonable expectation of success in combining the references. On the contrary, Jaber states on page S53 that "[t]o date, however, no treatment has been able to show consistent and reproducible benefit in clinical trials. Currently, the US Food and Drug Administration has not approved any of these adsorptive-based therapies for sepsis." Thus, there was a great need for the claimed method, and that was so for many years despite the availability of adsorption technology. Applicants answered this need by recognizing that a fluidized bed system could provide an effective solution.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

By  \_\_\_\_\_

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